

Application Number 10/656,855
Amendment in Response to Office Action mailed December 22, 2006

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REMARKS

This Amendment is responsive to the Final Office Action dated December 22, 2006. Applicant has canceled claims 35 and 36. Claims 11, 12, 14-34 and 37-41 will be pending upon entry of this Amendment.

Applicant respectfully requests entry of this after-final Amendment. This Amendment involves only the cancellation of claims, and therefore neither raises new issues nor requires any further search. Furthermore, Applicant submits that this Amendment places the application in better condition for allowance or appeal by rendering an objection to the specification made in the Final Office Action moot.

Objection to the Specification

In the Final Office Action, the Examiner objected to the specification as failing to provide proper antecedent basis for "applying a frictional force to the luminal surface in the absence of frozen liquid to lift nodes," as recited in independent claim 35 as previously presented. Applicant has canceled independent claim 35, as well as dependent claim 36. Applicant submits that the objection is therefore moot, and respectfully requests that it be withdrawn.

Applicant has canceled claims 35 and 36 for the purpose of expediting allowance of the present application and/or reducing the number of issues for appeal. Applicant does not acquiesce in the objection to the specification. Applicant reserves the right to present the subject matter of these cancelled claims during subsequent prosecution of the present application, or in another application claiming priority from the present application.

Claim Rejections Under 35 U.S.C. § 102

In the Final Office Action, the Examiner rejected claims 11, 12, 14-17, 19-22, 31-24, 36-41 under 35 U.S.C. § 102(b) as being anticipated by US 4,596,577 to Sato (Sato). The Examiner also rejected claims 19, 23, 24-30, 33-36 under 35 U.S.C. § 102(b) as being anticipated by US 6,352,555 to Dzau et al. (Dzau). Applicant respectfully traverses these rejections. Sato and Dzau fail to disclose each and every feature of the claimed invention, as required by 35 U.S.C. § 102(b), and provide no teaching that would have suggested the desirability of modification to include such features.

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Independent claim 11

Independent claim 11 recites a method comprising rubbing a luminal surface of a vascular prosthesis with a tool to lift nodes from the luminal surface to define a plurality of recesses. The Examiner rejected claim 11 under section 102(b) as being anticipated by Sato.

As stated in Applicant's previous submission, Sato does not teach or suggest lifting nodes from the luminal surface. Instead, Sato teaches rubbing techniques that result in a raised "nap...formed by fibrils from the original film, and partly torn material...."¹ Raising fibrils and partially torn material is not the same as raising nodes. Thus, Sato clearly fails to explicitly teach the requirements of independent claim 11.

The Examiner apparently acknowledged the failure of Sato to explicitly teach the requirements of claim 11, and therefore argued that lifting nodes above a luminal surface is inherent in the nap-formation techniques taught by Sato. More particularly, the Examiner argued that, because it is known that PTFE includes interconnected nodes and fibrils, "it must be inherent [that] the fibrils lift the nodes with them [when the fibrils are raised according to the Sato nap-forming process] since they are connected." Applicant respectfully disagrees with this argument.

The Examiner has provided no evidence or reasoning to suggest that nodes being lifted with fibrils is the only, or even the most likely, result of lifting fibrils according to the Sato method.² Other possible results of lifting fibrils according to the Sato method include stretching fibrils or breaking fibrils without lifting the nodes to any degree. In fact, the teaching in Sato of a "nap...formed by fibrils from the original film, and partly torn material" appears to be most consistent with stretched and/or torn fibrils.

The Court of Appeals for the Federal Circuit has held that a finding of inherency is improper when the allegedly inherent teaching is merely one of a number of possibilities. For example, the Court has held:

To establish inherency, the extrinsic evidence "must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by mere probabilities or possibilities. The mere

¹ Sato, col. 4, ll. 12-14.

² See MPEP 2112 (the Examiner is required to provide evidence or a rationale tending to show inherency).

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fact that a certain thing may result from a given set of circumstances is not sufficient.”³

This authority is directly on point with the present case. Incidental lifting of nodes while lifting fibrils to create a nap according to the Sato method is, at best, a mere possibility. Therefore, it is legally impermissible for the Examiner to argue that “lifting nodes from the surface to define a plurality of recesses,” as required by independent claim 11, is inherently present in Sato.

Independent claims 19 and 25

Similar to independent claim 11 discussed above, independent claim 19 recites a method comprising applying a frictional force to a medical device, the medical device adapted to be implanted in a human body and including at least one surface including expanded polytetrafluoroethylene, to lift nodes from the surface to define a plurality of recesses. Also similar to independent claim 11, independent claim 25 recites a method comprising applying a frictional force to a medical device, the medical device adapted to be implanted in a human body and including at least one surface comprising nodes formed of polytetrafluoroethylene, to lift nodes from the surface to define a plurality of recesses. The Examiner rejected independent claims 19 and 25 under section 102(b) as being anticipated by Sato. For the reasons discussed above with respect to claim 11, Sato fails to disclose or suggest the requirements of independent claims 19 and 25.

The Examiner also rejected independent claims 19 and 25 under section 102(b) as being anticipated by Dzau. Like Sato, Dzau fails to mention lifting nodes from a luminal surface to create recesses. Unlike Sato, Dzau does not even discuss lifting anything from the luminal surface.

Nonetheless, the Examiner argued that force of fluid containing cells injected into a lumen of a prosthesis as a sodding medium would inherently cause nodes to be lifted from the luminal surface. More particularly, the Examiner argued that “[i]t is inherent that the force of the fluid causes the nodes to be lifted from the surface since recesses have been formed and the cells adhered and filled them.” Applicant respectfully disagrees. Neither the presence of recesses in the Dzau prosthesis, nor the use of a pressure gradient to force the injected fluid through the luminal wall, would necessarily result in, or is even remotely suggestive of lifting nodes above

³ *In re Robertson*, 49 USPQ2d 1449, 1450-51 (Fed. Cir. 1999) (citations omitted).

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the luminal surface. Consequently, it is not at all clear to Applicant why the Examiner would cite these features of Dzau as supporting a conclusion that injecting a sodding medium as taught by Dzau necessarily results in lifting nodes above the Dzau prosthesis surface.

Stated another way, Applicant respectfully suggests that the teachings of Dzau would not have even suggested to a person of ordinary skill in the art that lifting nodes from the luminal surface was a possible result of the injection of fluid. Rather, such an operation would have been apparent only with the benefit of hindsight in view of Applicant's disclosure. The teachings of Dzau certainly would not have led such a person to conclude that nodes were certainly or necessarily lifted from the Dzau luminal surface to create recesses when a sodding medium was injected into the Dzau prosthesis lumen.

Furthermore, contrary to the requirements of claims 19 and 25, the recesses formed in the Dzau prosthesis are formed by stretching, prior to injection of the sodding medium. Thus, even if the injection of a sodding medium as taught by Dzau resulted in the application of some force to the luminal surface of the Dzau prosthesis, it would not define a plurality of recesses, as required by claims 19 and 25. In other words, Dzau is clear that the only recesses on the Dzau device are defined by stretching, which occurs prior to injection of fluid, and are not defined by the injection of the fluid.⁴ The Examiner apparently recognized this difference between the teachings of Dzau and the requirements of claim 19 and 25, when the Examiner stated "it is inherent that the force of fluid causes the nodes to be lifted from the surface since recesses have been formed...."⁵

Independent claim 33

Independent claim 33 recites a method for treating a luminal surface of a vascular prosthesis that comprises expanded polytetrafluoroethylene, the luminal surface comprising nodes and fibrils, the method comprising applying a frictional force to the luminal surface to lift at least some of the nodes from the luminal surface and form recesses, wherein the lifted nodes are substantially free of attached fibrils. Thus, similar to independent claims 11, 19 and 25, independent claim 33 requires applying a frictional force to the luminal surface to lift nodes from

⁴ Dzau, col. 5, ll. 13-18.

⁵ Emphasis added.

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the luminal surface and form recesses. For the reasons discussed above, Sato and Dzau fail to disclose this requirement, either expressly or inherently.

Independent claim 33 further recites "wherein the lifted nodes are substantially free of attached fibrils." Sato and Dzau both fail to disclose or suggest this further limitation of independent claim 33. Furthermore, the Final Office Action did not address this further limitation of claim 33, which suggests that the Examiner did not consider it. For at least these reasons, the rejection of claim 33 and/or the finality of the Office Action should be withdrawn.

Independent claim 37

Independent claim 37 recites a method for treating a luminal surface of a vascular prosthesis that comprises expanded polytetrafluoroethylene, wherein the luminal surface comprises nodes and fibrils oriented to interconnect the nodes, and wherein the vascular prosthesis has a generally tube-shaped structure having an axis, the method comprising rubbing the luminal surface with a brush in a direction that is substantially parallel to the axis of the vascular prosthesis and the oriented fibrils to lift the nodes from the luminal surface and form recesses. Thus, similar to the independent claims discussed above, independent claim 37 requires rubbing a luminal surface to lift nodes from the luminal surface and form recesses. The Examiner rejected claim 37 under section 102(b) as being anticipated by Sato. For the reasons discussed above, Sato fails to disclose this requirement, either expressly or inherently.

Independent claim 37 further requires that the rubbing be in a direction that is substantially parallel to both the axis of the vascular prosthesis and oriented fibrils of the luminal surface. As stated in Applicant's previous response, Sato does not even mention the orientation of fibrils, and is completely silent regarding a direction for the described brushing. Thus, Sato does not even remotely suggest rubbing in a direction that is substantially parallel to both the axis of the vascular prosthesis and oriented fibrils of the luminal surface, as required by independent claim 37.

Nonetheless, the Examiner rejected claim 37 in the Final Office Action. In support of the rejection of claim 37, the Examiner argued that "substantially parallel" is "terminology of relative degree, which has no basis of comparison," and therefore "considered broad and relatively unlimited in how it can be interpreted." In other words, the Examiner argued that it does not matter that Sato fails to disclose or suggest rubbing in a direction that is substantially

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parallel to both the axis of the vascular prosthesis and oriented fibrils of the luminal surface, because the term substantially parallel can be interpreted as broadly as needed to find anticipation. In this case, because Sato does not disclose any direction for brushing, the Examiner apparently construed the requirement in claim 37 of rubbing in a direction that is substantially parallel to both the axis of the vascular prosthesis and oriented fibrils of the luminal surface so broadly as to effectively read it out of the claim entirely.

This claim construction and finding of anticipation is reversible error. Applicant can find no authority that supports the Examiner's argument that that "substantially parallel" is "terminology of relative degree, which has no basis of comparison," and therefore "considered broad and relatively unlimited in how it can be interpreted." Moreover, although claims may be given their broadest reasonable interpretation consistent with the specification, the Federal Circuit has repeatedly held that it is improper to interpret a claim limitation so broadly as to effectively remove it from the claim.⁶ Additionally, with respect to the interpretation of relative terminology, the USPTO has stated "[w]hile *generally* and other similar words are sometimes construed liberally to avoid unduly restricting a patent claim, the imprecision of such a term cannot be allowed to negate the meaning of the word it modifies."⁷ Accordingly, in this case, it is improper for the Examiner to construe the term "substantially" so broadly as to read the phrase "parallel to the axis of the vascular prosthesis and the oriented fibrils" out of claim 37, as would be necessary to find that Sato anticipates claim 37.

Claims 21, 31, 32 and 34

Similar to independent claim 37, claims 21, 31, 32 and 34 include limitations that recite directions for application of frictional force or rubbing using the term "substantially." As was the case for independent claim 37, the Examiner's rejection of claims 21, 31, 32 and 34 is entirely dependent on an unduly broad interpretation of the term "substantially," which, for the reasons discussed above with respect to claim 37, is legally improper.

⁶ See, e.g., *Texas Instruments, Inc. v. U.S. Int'l Trade Comm'n*, 26 USPQ2d 1018 (Fed. Cir. 1993); *Ethicon Endo-Surgery, Inc. v. U.S. Surgical Corp.*, 40 USPQ2d 1019 (Fed. Cir. 1996) (recognizing that meaning must be given to all words in the claims); *Lockheed Martin Corp. v. Space Systems/Loral, Inc.*, 58 USPQ2d 1671 (Fed. Cir. 2001); *Innova/Pure Water, Inc. v. Safari Water Filtration Systems, Inc.*, 72 USPQ2d 1001 (Fed. Cir. 2004).

⁷ Patent Examination Policy – MPEP Staff, www.uspto.gov/web/offices/pac/dapp/35usc112.htm (further stating as an example that "generally planar" would allow irregular deviations from a perfectly flat surface, but could not broaden the meaning of planar to encompass distinctly arcuate surfaces.)

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Claim 16

Claim 16, which depends from claim 11, recites "wherein rubbing [to lift nodes] comprises moving the bristles in the luminal direction." The Examiner rejected claim 16 under section 102(b) as anticipated by Sato.

As discussed above, Sato is completely silent regarding a direction for the described brushing. Further, a person of ordinary skill would not have considered the Sato method to necessarily involve any of the numerous possible brushing directions, much less the particular direction recited in claim 16. Thus, in accordance with clear Federal Circuit precedent discussed above, the requirements of claim 16 are not inherent in the Sato disclosure.

In the Final Office Action, the Examiner attempted to bolster the argument that rubbing by moving bristles in the luminal direction is inherent in Sato. More particularly, the Examiner argued "any application of a rotary brush along the length of the tubular body inherently is going to pass along the axis." Applicant respectfully suggests that the Examiner is finding teachings in Sato that simply are not there.

For example, the Examiner's argument is premised on the "fact" that the Sato brush is moved along the length of the Sato tubular body. However, Sato does not teach or suggest that the brush is moved along the length of the tubular body. With respect to the tube of FIG. 4, Sato merely states that that "[t]he nap can be provided on the outer surface of the tube 11, or both the inner and outer surfaces thereof."⁸

Furthermore, moving the brush along the length of the tubular body is not inherent in the Sato method. In addition to failing to discuss the direction in which the bristles move during rubbing, Sato fails to discuss the relative sizes of tubular body and brush, the extent to which the inner surface of the tubular body would be brushed, or anything else that would suggest that the brush would necessarily be moved in the luminal direction during brushing. Moreover, even if the Sato brush were moved in the luminal direction, such movement would still not necessarily include rubbing by moving bristles in the luminal direction, because it would also be possible to lift the brush off of the luminal surface during movement in that direction.

⁸ Sato, col. 4, ll. 32-34.

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For at least these further reasons, and in accordance with the clear Federal Circuit precedent discussed above, rubbing to lift nodes by moving bristles in the luminal direction is not inherent in the Sato disclosure.

Sato and Dzau fail to disclose each and every limitation set forth in a number of Applicant's claims, including each of independent claims 11, 19, 25, 33 and 37. For at least the reasons discussed above, the Examiner has failed to establish a prima facie case for anticipation of Applicant's claims 11, 12, 14-17, 19-34, 37 and 39-41 under 35 U.S.C. § 102(b). Withdrawal of this rejection is requested.

Claim Rejection Under 35 U.S.C. § 103

In the Final Office Action, the Examiner rejected claims 18 and 38 under 35 U.S.C. § 103(a) as being unpatentable over Sato. Applicant respectfully traverses the rejection. Sato fails to disclose or suggest the inventions defined by Applicant's claims, and provides no teaching that would have suggested the desirability of modification to arrive at the claimed invention.

Claims 18 and 38 both require that the luminal surface of the vascular prosthesis is the outer surface when the prosthesis is rubbed to lift nodes from the surface. Claims 18 and 38 both further require that the prosthesis is everted after rubbing.

Initially, Applicant notes that each of claims 18 and 38 depends from one of independent claims 11 and 37, and is patentable over Sato for at least the reasons discussed above with respect to those independent claims. Further, the Examiner's arguments in support of a prima facie case of obviousness for these claims lack evidentiary support and are legally improper.

In rejecting claims 18 and 38, the Examiner acknowledged that Sato fails to disclose or suggest these limitations of claims 18 and 38, but argued that it would have been an obvious matter of "design choice" to modify the Sato method to rub the Sato prosthesis with the luminal surface as the outer surface and then evert the prosthesis, "since applicant has not disclosed that using an everted prosthesis provides any advantage, or solves a stated problem, or is used for any particular purpose."

As stated in Applicant's previous submission with respect to other rejections now withdrawn, unsupported assertions of "design choice" are contrary to clear Federal Circuit

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precedent, which holds that a finding of obviousness must be based upon substantial evidence, and not subjective musings or conjecture by the Examiner.⁹ Consequently, unless the Examiner can establish an evidentiary record based on concrete prior art references that establish that it would have been obvious to a person with ordinary skill to modify the Sato method to include brushing and then everting a prosthesis, the rejection of claims 18 and 38 should be withdrawn.

Furthermore, as stated in Applicant's previous submission with respect to other rejections now withdrawn, it is also legally improper for the Examiner to find claims 18 and 38 to be obvious based on whether or not Applicant has "disclosed that using an everted prosthesis provides any advantage, or solves a stated problem, or is used for a particular purpose." Whether a requirement of Applicants' claims is obvious depends upon what is taught in the prior art, rather than Applicant's disclosure¹⁰.

Moreover, the Examiner's characterization of Applicant's disclosure is incorrect. For example, at paragraph [0061], the disclosure states:

It is believed to be possible to rub a luminal surface without everting the prosthesis, e.g., by running a brush through the lumen one or more times. Accordingly, everting the prosthesis for processing is not essential to the invention. Even so, mounting the prosthesis on a supporting mandrel, as shown in FIG. 2, may allow for very precise control of the rubbing.

Further, paragraph [0063] describes an example in which "the prosthesis had been everted so that that luminal surface was more accessible."

For at least these reasons, the Examiner has failed to establish a prima facie case for non-patentability of Applicant's claims 18 and 38 under 35 U.S.C. § 103(a). Withdrawal of this rejection is requested.

⁹ *In re Lee*, 61 USPQ2d 1430 (Fed. Cir. 2002) (emphasis added).

¹⁰ *In re Oetiker*, 24 USPQ2d 1443, 1445 (Fed. Cir. 1992).

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All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims.

In view of the clear distinctions identified above between the current claims and the applied prior art, Applicant reserves further comment at this time regarding any other features of the independent or dependent claims. However, Applicant does not necessarily admit or acquiesce in any of the rejections or the Examiner's interpretations of the applied references. Applicant reserves the right to present additional arguments with respect to any of the independent or dependent claims.

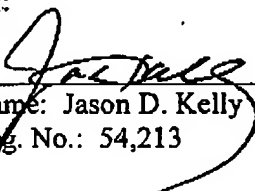
Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

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2-22-07

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